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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/493,480	01/28/00	CHEEVER M	0140580-0098

EXAMINER	
HUNT, J	
ART UNIT	**PAPER NUMBER**
1642	9

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DATE MAILED: 03/20/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/493,480	Applicant(s) Cheever et al.
	Examiner Jennifer Hunt	Group Art Unit 1642

☐ Responsive to communication(s) filed on _____ .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-92* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-92* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 10-14, 26-32, and 35-39, drawn to a fusion protein comprising an extracellular domain and fragment thereof and a phosphorylation domain, classified in class 530, subclass 350.

II. Claims 8-9, 15-18, 33, 34, 40-43, and 89-92, drawn to a polynucleotide encoding an extracellular domain and fragment thereof and a phosphorylation domain, vector, and method of making a polypeptide, classified in class 536, subclass 23.5, class 435, subclass 320.1, 325 and 69.1.

III. Claims 19-20, 44-45, and 76, drawn to a method of treatment by administering a polypeptide comprising an extracellular domain, classified in class 514, subclass 2.

IV. Claims 21-25, 46-50, and 77, drawn to a method of treatment by administering a polynucleotide encoding an extracellular domain, classified in class 514, subclass 44.

V. Claims 51-57, and 60-64, drawn to a fusion protein comprising an intracellular domain and fragment thereof and a phosphorylation domain, classified in class 530, subclass 350.

VI. Claim 58, 59, 65-68, and 89-92, drawn to a polynucleotide encoding an extracellular domain and fragment thereof and a phosphorylation domain, vector, and method of making a polypeptide, classified in class 536, subclass 23.5, class 435, subclass 320.1, 325 and 69.1.

VII. Claims 69-70, 76, and 80, drawn to a method of treatment by administering a polypeptide comprising an intracellular domain, classified in class 514, subclass 2.

VIII. Claims 71-75, 77 and 80, drawn to a method of treatment by administering a polynucleotide encoding an extracellular domain, classified in class 514, subclass 44.

IX. Claims 78-80, drawn to a method of treatment by administering antigen presenting cells, classified in class 424, subclass 93.1.

X. Claims 81-83, drawn to a method of removing tumor cells using a T cell which reacts with a fusion protein comprising a HER2/neu extracellular domain and a phosphorylation domain, classified in class 435, subclass 372.

XI. Claims 84-88, drawn to a method of stimulating T cells and treating a patient using the stimulated T cells, classified in class 424, subclass 93.71.

2. The inventions are distinct, each from the other because of the following reasons:

The products of Groups I, II, V and VI are completely different products, having different structures and different biological functions. A fusion protein or nucleic acid comprising an

extracellular domain (Groups I and II) is distinct from a fusion protein or nucleic acid encoding an intracellular domain (Groups V and VI) because extracellular domains and intracellular domains have completely different amino acid and nucleic acid sequences, locations, functions and properties. Further nucleic acids are completely different from proteins in the structure, biological functions and properties.

The methods of Groups III, IV, and VII-XI are completely different methods, having different starting points, different method steps, and different outcomes. The methods of Groups III, IV, and VII-VIII are all drawn to treatment methods, however they use completely different compositions for treatment. A method of treatment using fusion protein or nucleic acid comprising an extracellular domain (Groups III and IV) is distinct from a method of treatment using a fusion protein or nucleic acid encoding an intracellular domain (Groups VII and VIII) because extracellular domains and intracellular domains have completely different amino acid and nucleic acid sequences, locations, functions and properties, and would act differently when administered for treatment. Further nucleic acids are completely different from proteins in the structure, biological functions and properties, and would act differently when administered for treatment. Further, the method of Group IX uses an antigen presenting cell for treatment. This treatment method uses an entirely different composition for treatment which would act differently when administered. Group X is drawn to a method of removing tumor cells which is a completely different objective and has different method steps from the aforementioned and subsequent methods. Lastly, the method of Group XI is a method of stimulating T-cells using

any number or combination of various compositions which has distinct reactants and outcomes from the aforementioned methods. Thus the methods are distinct as set forth above, and require different searches and grounds of consideration.

3. Inventions of Groups I or V and III or VII respectively are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins of Groups I and V can be used for a materially different process, such as to generate antibodies or to stimulate T cells.

4. Inventions of Groups II or VI and Groups IV or VIII respectively are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Groups II or VI can be used for a materially different process, such as to express polypeptide or stimulate T-cells.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for any one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

If the invention of Groups I, II, V, or VI is elected, applicant must further elect from species of extracellular domain:

a. The full length extracellular domain

b. A fragment of the extracellular domain.

These domains are distinct because the resulting proteins will have different structural and functional properties, and require distinct searches and grounds of consideration.

If the invention of Group XI is elected, applicant must further elect a species of T cell stimulant:

a. Fusion polynucleotide encoding the full length extracellular domain.

b. Fusion polynucleotide comprising a fragment of the extracellular domain.

c. Fusion polynucleotide comprising the intracellular domain.

These compositions are distinct and would result in different T cell responses.

If the invention of Group XI is elected, applicant must further elect a species of T cell stimulant:

a. Fusion polypeptide comprising the full length extracellular domain.

b. Fusion polypeptide comprising a fragment of the extracellular domain.

c. Fusion protein comprising the intracellular domain.

d. Fusion polynucleotide encoding the full length extracellular domain.

e. Fusion polynucleotide comprising a fragment of the extracellular domain.

f. Fusion polynucleotide comprising the intracellular domain.

g. Antigen presenting cells which express a fusion polypeptide comprising the full length extracellular domain.

h. Antigen presenting cells which express a fusion polypeptide comprising a fragment of the extracellular domain.

I. Antigen presenting cells which express a fusion protein comprising the intracellular domain.

These compositions are distinct and would result in different T cell responses.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. A telephone call was made to on to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Hunt, whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. The fax number for the group is (703) 305-3014 or (703) 308-4242.

Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**anthony.caputa@uspto.gov**].

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Hunt

March 19, 2001

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SUPERVISORY PATENT EXAMINER
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